

REMARKS

The Office Action of October 5, 2004, has been received and reviewed.

Claims 34-120 are currently pending and under consideration in the above-referenced application. Of these, claims 100-109 have been allowed, claims 46, 48-51, 61, 62, 65-69, 78, 80-83, 85-87, 95-99, 111, and 116-120 are objected to for depending from rejected base claims, and claims 34-45, 47, 52-60, 63, 64, 70-77, 79, 84, 88-94, 110, and 112-115 stand rejected.

Claim 71 has been canceled without prejudice or disclaimer.

Reconsideration of the above-referenced application is respectfully requested.

Claim Amendments

Each incidence of the terms “patient” and “individual” has been replaced with the term “subject” in the claims. These revisions do not narrow the scope of any of the claims, as the term “subject” is broader than the terms “patient” and “individual.”

Other claim amendments are discussed in further detail in the ensuing remarks.

Claim Objection

The Office has objected to Claim 71 under 37 C.F.R. § 1.75(c) for purportedly being of improper dependent form for failing to further limit the subject matter of a previous claim.

Claim 71 has been canceled without prejudice or disclaimer, rendering the objection thereto moot. Accordingly, withdrawal of the 37 C.F.R. § 1.75(c) objection to claim 71 is respectfully requested.

Rejections Under 35 U.S.C. § 102

Claims 34-42, 44, 45, 47, 70-74, 76, 77, and 79 stand rejected under 35 U.S.C. § 102(e).

A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single reference which qualifies as prior art under 35 U.S.C. § 102. *Verdegaal Brothers v. Union Oil Co. of California*, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). The identical invention must be shown in as complete detail as is contained in the claim. *Richardson v. Suzuki Motor Co.*, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989).

Gama De Abreu

Claims 34, 35, 37-42, 44, 45, 47, 70-74, 76, 77, and 79 stand rejected under 35 U.S.C. § 102(e) for reciting subject matter which is allegedly anticipated by the subject matter disclosed in U.S. Patent 6,106,480 to Gama De Abreu et al. (hereinafter “Gama De Abreu”).

Gama De Abreu describes techniques for noninvasively determining pulmonary cardiac blood flow by measuring CO₂ elimination (VCO₂) and end-tidal, or expiration termination, CO₂ partial pressure (PetCO₂) over a nonrebreathing period that lasts for 60 seconds and the last fifteen seconds of a thirty second rebreathing period. Col. 2, lines 40-57.

Independent claim 34 is directed to a method which includes “evaluating respiration of [a] subject during a first ventilation state” and “evaluating respiration of the subject during a second ventilation state.” As amended and presented herein, the first and second ventilation states that are recited in independent claim 34 both have durations of “about eighteen to about forty-two seconds.”

Gama De Abreu does not expressly or inherently describe first *and* second ventilation status that both have durations of about eighteen to about forty-two seconds. Rather, the description of Gama De Abreu is limited to a nonrebreathing period that lasts for sixty seconds, which is significantly greater than forty-two seconds, and a thirty second rebreathing period. As such, Gama De Abreu does not anticipate each and every element of amended independent claim 34.

It is, therefore, respectfully submitted that the subject matter to which amended independent claim 34 is directed is allowable over the subject matter described in Gama De Abreu.

Claims 35, 37-42, 44, 45, and 47 are each allowable, among other reasons, for depending directly from claim 34, which is allowable.

Independent claim 70, as amended and presented herein, recites a differential Fick technique that includes a first phase in which a change in the effective ventilation of a subject is

induced and a second phase, which follows the first phase, of substantially the same duration as the first phase and in which a change in effective ventilation is not present.

In contrast to the subject matter recited in amended independent claim 70, the disclosure of Gama De Abreu is limited to a process in which VCO₂ and PetCO₂ are monitored during a first, nonbreathing period (*i.e.*, a period in which there is no change in effective ventilation of a subject), which is followed by a second rebreathing period (*i.e.*, a period in which a change in effective ventilation is induced).

Moreover, Gama De Abreu lacks any express or inherent description that the nonbreathing and rebreathing periods mentioned therein have substantially the same durations. Rather, the nonbreathing period of Gama De Abreu lasts for sixty seconds, while the rebreathing period lasts for thirty seconds.

For these reasons, Gama De Abreu does not anticipate each and every element of amended independent claim 70, as would be required to maintain the 35 U.S.C. § 102(e) rejection thereof.

Claim 71 has been canceled without prejudice or disclaimer, rendering the rejection thereof moot.

Each of claims 72-74, 76, 77, and 79 is allowable, among other reasons, for depending directly from claim 70, which is allowable.

Claim 72 is further allowable since Gama De Abreu includes no express or inherent description that the nonbreathing period thereof has a duration of about thirty seconds. Rather, the description of Gama De Abreu is limited to a technique that includes a nonbreathing period that lasts for sixty seconds.

Kück

Claims 34-42, 44, 45, 47, 70-74, 76, 77, and 79 stand rejected under 35 U.S.C. § 102(e) for reciting subject matter which is allegedly anticipated by the disclosure of U.S. Patent 6,200,271 to Kück et al. (hereinafter "Kück").

Kück, at col. 9, lines 31-42, describes an exemplary "bi-directional rebreathing" process that includes a "before" phase that last for six seconds (the difference between the time at 40

seconds into the process and the time at 46 seconds into the process). The subsequent “during” phase lasts for about 50 seconds. Col. 9, lines 43-51. Kück is silent as to the specific length of the “after” phase, which occurs following the “during” phase. *See* Col. 9, lines 52-60 (which merely states that the “after” phase “may be of any duration sufficient to facilitate the accurate determination of VCO_2 and $CACO_2$ ”).

The Office has also noted that Figs. 4 and 5 of Kück show a “before rebreathing” phase that during which respiration is evaluated for about 50 seconds, a “during rebreathing” phase that lasts for about 60 seconds, and an “after rebreathing” phase in which rebreathing is monitored for about 40 seconds.

With respect to the subject matter recited in amended independent claim 34, Kück lacks any express or inherent description of a method which includes evaluating respiration during first and second ventilation states that each last for about eighteen seconds to about forty-two seconds. Instead, the description of Kück is limited to evaluating respiration for a first state that lasts for six seconds, a second state that lasts for about 50 seconds, and a third state that lasts for an undefined period of time, or to evaluating respiration for first, second, and third states that respectively last for 50 seconds, 60 seconds, and 40 seconds.

Therefore, Kück does not anticipate each and every element of any of amended independent claim 34. Accordingly, it is respectfully submitted that, under 35 U.S.C. § 102(e), amended independent claim 34 recites subject matter which is allowable over that described in Kück.

Each of claims 35-42, 44, 45, and 47 is allowable, among other reasons, for depending directly or indirectly from claim 34, which is allowable.

Claim 36 is additionally allowable since Kück does not expressly or inherently describe “repeating evaluating respiration of [a] subject during another first ventilation state *immediately following* evaluating respiration of the subject during [a] second ventilation state.” (Emphasis supplied). Instead, Kück describes evaluating respiration of a subject during a first state (the “before” phase), then a second state (the “during” phase), then a third state (the “after” phase).

Claim 45 is further allowable because Kück includes no express or inherent description of evaluating respiration of a subject during a second ventilation state in which the subject breathes

“gas or a gas mixture comprising at least a concentration of oxygen present in air.” Instead, the description of Kück is limited to a second ventilation state in which a subject breathes gases with an increased concentration of carbon dioxide.

With respect to the subject matter recited in independent claim 70, Kück does not expressly or inherently describe a differential Fick technique that includes two phases of substantially the same duration. Instead, the description of Kück is limited to a bi-directional rebreathing process that includes a first (“before”) phase, a second (“during”) phase, and a third (“after”) phase. The only description provided in Kück with respect to the lengths of these phases is that the “before” phase lasts for six seconds and the “during” phase lasts for about 50 seconds (*see* col. 9, lines 31-51), or that these phases may last for 50 seconds, 60 seconds, and 40 seconds, respectively (Figs. 4 and 5).

Therefore, it is respectfully submitted that the description provided by Kück does not anticipate each and every element of independent claim 70, as would be required to maintain the 35 U.S.C. § 102(e) rejection of that claim.

Claim 71 has been canceled without prejudice or disclaimer, rendering moot the rejection thereof.

Claims 72-74, 76, 77, and 79 are each allowable, among other reasons, for depending directly from claim 70, which is allowable.

Claim 72 is also allowable because Kück lacks any express or inherent description of first and second phases that both have durations of about thirty seconds. Rather, the description of Kück is limited to a “before” phase that lasts for six seconds and a “during” phase that lasts for about 50 seconds, and to a “before” phase that lasts for 50 seconds and a “during” phase that lasts for 60 seconds..

In view of the foregoing, it is respectfully requested that the 35 U.S.C. § 102(e) rejections of claims 34-42, 44, 45, 47, 70-74, 76, 77, and 79 be withdrawn.

Rejections Under 35 U.S.C. § 103(a)

Claims 43, 52-60, 63, 64, 84, 88-94, 110, and 112-115 stand rejected under 35 U.S.C. § 103(a).

The standard for establishing and maintaining a rejection under 35 U.S.C. § 103(a) is set forth in M.P.E.P. § 706.02(j), which provides:

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

With respect to rejections under 35 U.S.C. § 103(a) that are based upon references which qualify as prior art under 35 U.S.C. § 102(e), 35 U.S.C. § 103(c) provides:

Subject matter developed by another person, which qualifies as prior art only under one or more of subsections (e), (f), and (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

M.P.E.P. § 706.02(l)(1) indicates that 35 U.S.C. 103(c) applies to all applications which have filing or priority dates of November 29, 1999, or later:

This change to 35 U.S.C. 103(c) applies to all utility, design and plant patent applications filed on or after November 29, 1999, including continuing applications filed under 37 CFR 1.53(b), continued prosecution applications filed under 37 CFR 1.53(d), and reissues.

Gama De Abreu in View of Orr

Claim 43 has been rejected under 35 U.S.C. § 103(a) for reciting subject matter which is purportedly unpatentable over the subject matter taught in Gama De Abreu, in view of teachings from U.S. Patent 6,540,689 to Orr et al. (hereinafter "Orr").

The above-referenced application has a filing date of March 20, 2001, and, therefore, may benefit from the provisions of 35 U.S.C. § 103(c).

Orr issued from an application that was filed on February 22, 2000, before the filing date of the above-referenced application, but did not issue until April 1, 2003, well after the above-referenced application was filed. Therefore, Orr only qualifies as prior art to the claims of the above-referenced application under 35 U.S.C. § 102(e).

At the time the invention disclosed in the above-referenced application was made, it was owned by or subject to an obligation of assignment to NTC Technology Inc., as evidenced by the assignment recorded at Reel 11642, Frame 571. NTC Technology Inc. is the same party to which Orr had already been assigned, as indicated by the cover sheet of Orr.

Accordingly, Orr may not be relied upon in a rejection of any of the claims of the above-referenced application under 35 U.S.C. § 103(a).

In any event, claim 43 is allowable, for depending from claim 34, which is allowable.

Withdrawal of the 35 U.S.C. § 102(e) rejection of claim 43 is, therefore, respectfully requested.

Kück

Claims 52-60, 63, 64, 84, 88-94, 110, and 112-115 have been rejected under 35 U.S.C. § 103(a) for being drawn to subject matter which is assertedly unpatentable over the subject matter taught in Kück.

The Office has noted, at page 11 of the Office Action of October 5, 2004, that Kück qualifies as prior art only under 35 U.S.C. § 102(e). While the above-referenced application was not filed until March 20, 2001, one week after the date on which Kück issued, the subject matter disclosed in the above-referenced application, as well as that recited in claims 52-60, 63, 64, 84,

88-94, 110, and 112-115 was invented before the issue date of Kück. Thus, it is respectfully submitted that Kück is not 35 U.S.C. § 102(a) prior art.

At the time the invention disclosed in the above-referenced application was made, it was owned by or subject to an obligation of assignment to NTC Technology Inc., as evidenced by the assignment recorded at Reel 11642, Frame 571. NTC Technology Inc. is the same party to which Kück had already been assigned, as indicated by the cover sheet of Kück.

Accordingly, Kück may not be relied upon in a rejection of any of claims 52-60, 63, 64, 84, 88-94, 110, or 112-115 of the above-referenced application under 35 U.S.C. § 103(a).

In any event, it is respectfully submitted that a *prima facie* case of obviousness has not been set forth against any of claims 52-60, 63, 64, 84, 88-94, 110, or 112-115. In particular, it is respectfully submitted that Kück does not teach or suggest each and every element of any of claims 52-60, 63, 64, 84, 88-94, 110, or 112-115.

Independent claim 52 is drawn to a method for noninvasively estimating at least one of a pulmonary capillary blood flow and a cardiac output of a patient. The method of independent claim 52 includes evaluating respiration of a patient during first and second ventilation states. The second ventilation state immediately follows the first ventilation state. Then, immediately following the second ventilation state, respiration of the patient is evaluated during another first ventilation state. Independent claim 52, as amended and presented herein, also recites that each of the first, second, and another first ventilation states has a duration of about eighteen seconds to about forty-two seconds.

Independent claim 110 also recites a method for noninvasively determining at least one of a pulmonary capillary blood flow and a cardiac output of a patient. The method of independent claim 110 includes evaluating respiration of the patient during each of a first phase and a second phase. During the first phase, which lasts for a first duration of time, a change in effective ventilation of the patient is induced. During the second phase, which lasts for a second period of time, the change in effective ventilation is removed. Independent claim 110, as amended and presented herein, also recites that the first and second phases each last for about eighteen seconds to about forty-two seconds.

With respect to the subject matter recited in amended independent claims 52 and 110, Kück lacks any teaching or suggestion of a method which includes evaluating respiration during first and second ventilation states (claim 52) or phases (claim 110) that each last for about eighteen seconds to about forty-two seconds. Instead, the teachings of Kück are limited to evaluating respiration for a first state that lasts for six seconds or 50 seconds, a second state that lasts for about 50 seconds or 60 seconds, and a third state that lasts for 40 seconds.

Therefore, it is respectfully submitted that, under 35 U.S.C. § 103(a), independent claims 52 and 110 recite subject matter which is allowable over that taught in Kück.

Each of claims 53-60, 63, and 64 is allowable, among other reasons, for depending either directly or indirectly from claim 52, which is allowable.

Claim 53 is also allowable since Kück neither teaches nor suggests that first and second ventilation states may be effected for substantially a same duration.

Claim 54 is further allowable since Kück does not teach or suggest that respiration may be evaluated during three ventilation states having substantially the same durations. Instead, Kück teaches that respiration may be evaluated during a first state that lasts for 50 seconds and a second state that lasts for 60 seconds, or during a first state that lasts for six seconds and a second state that lasts for 50 seconds.

Claims 55-57 are allowable because Kück includes no teaching or suggestion that respiration may be respectively evaluated during a first, second, or third ventilation state that lasts for about thirty seconds. Rather, Kück teaches that a first state in which respiration is evaluated lasts for six seconds or 50 seconds and a second state lasts for 50 seconds or 60 seconds, and a third state that may last for 40 seconds.

Claim 64 is further allowable because Kück includes no teaching or suggestion of evaluating respiration of a patient during a second ventilation state in which the patient breathes “gas or a gas mixture comprising at least a concentration of oxygen present in air.” Instead, the teachings of Kück are limited to a second ventilation state in which a patient breathes gases with an increased concentration of carbon dioxide.

Claims 113-115 are each allowable, among other reasons, for depending directly or indirectly from claim 110, which is allowable.

Independent claim 84 is also directed to a differential Fick technique. The differential Fick technique of independent claim 84, as amended and presented herein, includes inducing a change in effective ventilation of an individual for a duration of time of about eighteen seconds to about forty-two seconds. The change in effective ventilation is then removed for a second duration of time, which lasts for about eighteen seconds to about forty-two seconds. The second duration of time immediately follows the first duration of time. In addition, measurements of at least one respiratory gas and of respiratory flow are obtained during both the first duration and the second duration.

Kück includes no express or inherent description of a Fick technique which includes inducing a change in effective ventilation for a first duration of time, which lasts for about eighteen to about sixty seconds, removing the change in effective ventilation for a second duration of time, which also lasts for about eighteen to about sixty seconds, and obtaining gas and flow measurements during both the first and second durations of time.

It is, therefore, respectfully submitted that, under 35 U.S.C. 103(a), independent claim 84 is directed to subject matter which is allowable of that taught in Kück.

Claims 88-94 are each allowable, among other reasons, for depending either directly or indirectly from claim 84, which is allowable.

Claim 88 is also allowable since Kück neither teaches nor suggests that a first duration of time of inducing a change in effective ventilation and a second duration of time of removing a change in effective ventilation may substantially the same.

Claim 91 is also allowable since Kück does not teach or suggest that a change in effective ventilation may be induced for about thirty seconds and removed for about thirty seconds. Instead, Kück teaches that a “before rebreathing” state lasts for six seconds or 50 seconds and that a “rebreathing” state lasts for 50 seconds or 60 seconds, and that an “after rebreathing” state, or recovery period, that follows the “rebreathing state” may last for 40 seconds.

For these reasons, it is respectfully requested that the 35 U.S.C. § 103(a) rejections of claims 43, 52-60, 63, 64, 84, 88-94, 110, and 112-115 be withdrawn.

Allowable Subject Matter

The allowance of claims 100-109 and the indication that claims 46, 48-51, 61, 62, 65-69, 78, 80-83, 85-87, 95-99, 111, and 116-120 recite allowable subject matter are gratefully acknowledged. None of claims 46, 48-51, 61, 62, 65-69, 78, 80-83, 85-87, 95-99, 111, or 116-120 has been amended to independent form, as the claims from which they depend are believed to be allowable.

CONCLUSION

It is respectfully submitted that each of claims 34-70 and 72-120 is allowable. An early notice of the allowability of each of these claims is respectfully solicited, as is an indication that the above-referenced application has been passed for issuance. If any issues preventing allowance of the above-referenced application remain which might be resolved by way of a telephone conference, the Office is kindly invited to contact the undersigned attorney.

Respectfully submitted,



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